

Notice of Allowability

Application No.

09/998,822

Examiner

N. M. Minnifield

Applicant(s)

MENDOZA, ALBERTO L.

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 4/26/04; 7/09/04.
2. ☒ The allowed claim(s) is/are 4-12; now renumbered 1-9 respectively.
3. ☒ The drawings filed on 11/01/01 are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
 6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit
of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☒ Interview Summary (PTO-413),
Paper No./Mail Date attached.
7. ☒ Examiner's Amendment/Comment
8. ☐ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

N. M. Minnifield
Primary Examiner
Art Unit: 1645

EXAMINER'S AMENDMENT

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Ian C. McLeod, 20931 on July 9, 2004.

2. Applicant's arguments, see Appeal Brief, filed April 26, 2004, with respect to the 103 obviousness rejection have been fully considered and are persuasive. The 103 obviousness rejection of claims 4-12 have been withdrawn.

3. The application has been amended as follows:
Claims 1-3 (Canceled)

Claim 4. (Currently Amended) A method for treatment of pythiosis or against pythiosis in a mammal which prophylaxis comprises:

(a) providing an injectable vaccine which comprises in a sterile aqueous solution in admixture:

[(I)] (i) intracellular cytoplasmic antigens separated from disrupted cells *Pythium insidiosum* by SDS-PAGE; and

- (ii) extracellular antigens secreted into a medium for growing the cells of *Pythium insidiosum* wherein the mixture comprises 28, 30 and 32 kDa antigens as determined by SDS-PAGE; and
- (b) vaccinating the mammal with the vaccine.

Claim 5. (Currently Amended) The method of Claim 4 wherein the antigens have been provided by

- (a) growing cells of the *Pythium insidiosum* in a culture medium and then

- [(I)] (i) killing the cells;

- (ii) separating the killed cells from the culture medium so as to produce a first supernatant comprising the extracellular antigens secreted into the medium; and

- [(ii)] (iii) disrupting the cells water to provide the intracellular cytoplasmic antigens in a second supernatant which is separated from the disrupted cells; and

- (b) separating the extracellular antigens from the first supernatant.

Claim 6. (Original) The method of Claim 4 wherein the cells have been disrupted by sonication.

Claim 7. (Original) The method of Claim wherein the *Pythium insidiosum* is deposited as ATCC 74446.

Claim 8. (Original) The method of any one of Claims 5, 6, or 7 wherein the culture medium is Sabouraud dextrose broth.

Claim 9. (Original) The method of Claim 5 wherein the cells are killed with thimersol.

Claim 10. (Original) The method of Claim 5 wherein disrupted cells are separated from the culture medium for the cells by centrifugation.

Claim 11. (Original) The method of Claim 5 wherein the intracellular cytoplasmic antigens in the second supernatant and the extracellular antigens in the first supernatant are mixed to provide a mixture of antigens, precipitating the mixture of antigens with acetone to provide a precipitate, dissolving the precipitate in sterile distilled water to provide a solution of the antigens, and dialyzing the solution of antigens in sterile distilled water to remove low molecular weight components less than 10,000 MW to provide the vaccine.

Claim 12. (Currently Amended) The method of Claim 4 wherein the mammal after vaccination is monitored for a change in a Th1 response and a Th2 response, wherein an increase in Th1 response and a decrease in the Th2 indicates that the [patient] mammal has developed the Th1 response to the vaccine.

Claims 13-32 (Canceled)

4. Claims 4-12 are allowed and have been renumbered 1-9 respectively.

5. The following is an examiner's statement of reasons for allowance: the closest prior art of Mendoza et al. (1992, J. Clinical Microbiology, 30/11:2980-2983) in view of Mendoza et al. (1992, Micopathologia 119:89-95) does not provide a suggestion or motivation to one of ordinary skill in the art to combine the teachings of the references to produce and use a vaccine like the Applicant's for treating mammals. The present invention contains soluble intracellular proteins and the extracellular proteins in a mixture. Mendoza (Micopathologia teaches that the intracellular antigens are unstable and cause a prominent inflammatory reaction at the site of inoculation; this reference suggests that a vaccine comprising only the extracellular antigens would be immunodominant.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to N. M. Minnifield whose telephone number is 571-272-0860. The examiner can normally be reached on M-F (8:00-5:30) Second Friday Off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette R.F. Smith can be reached on 571-272-0864. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read "N. M. Minnifield", written over a printed name.

N. M. Minnifield

Primary Examiner

Art Unit 1645

NMM

July 9, 2004